

# NEWS RELEASE

**OFFICE OF THE UNITED STATES ATTORNEY  
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***For Immediate Release***

**FEBRUARY 11, 2005**

**SUBSIDIARY OF NOVARTIS PLEADS GUILTY TO  
NINE FELONY AUDIT OBSTRUCTION CHARGES  
AND IS SENTENCED WITH \$4.5 MILLION FINE**

**COMPANY ALSO REACHES CIVIL SETTLEMENT  
REQUIRING SEPARATE PAYMENT OF \$44,654,229**

Ronald J. Tenpas, United States Attorney for the Southern District of Illinois, announced on February 11, 2005 that OPI Properties, Inc., a subsidiary of Novartis Corporation ("Novartis"), pled guilty in the United States District Court for the Southern District of Illinois to nine felony counts of endeavoring to obstruct a federal audit.

Pursuant to the plea agreement, the United States and **OPI Properties, Inc.** agreed to recommend a sentence of five years probation and a criminal fine of \$4.5 million. Today, the Court accepted that sentencing recommendation, and imposed a sentence of a \$4.5 million fine with five years probation. Also announced today was a \$44,654,229 million civil settlement agreement between the United States and the Novartis Nutrition Company to resolve claims involving the Medicare program. The plea agreement requires **OPI Properties, Inc.** and the Novartis Nutrition Company to cooperate fully with the United States in connection with the Government's ongoing investigations and prosecutions of others for alleged violations of federal criminal and civil law.

Today's action marks the eleventh criminal conviction, including three by corporate subsidiaries of major health care providers, arising from "Operation Headwaters." Operation Headwaters was an undercover investigation by the Federal Bureau of Investigation, U.S. Postal Inspection Service, and

Office of Inspector General for the Department of Health and Human Services (“OIG”), in which federal agents created an entity known as Southern Medical Distributors (“SMD”). While operating, SMD acted as a distributor of medical supplies, and was approached by various manufacturers and distributors who offered inducements to undercover personnel to purchase enteral products. To date, including this case, Operation Headwaters’ probe of the enteral industry has recovered over \$670 million for the benefit of the United States and the Medicare and Medicaid programs.

United States Attorney Ronald J. Tenpas stated, “With today’s plea and sentence, we take another step toward cleaning up the enteral industry, changing the way the industry markets tube feeding equipment to our Nation’s seniors. We are committed to ensuring that practices in the enteral industry are transparent, allowing federal regulators to accurately determine the cost and charges incurred. This transparency is essential to an effective Medicare reimbursement system. We appreciate the efforts of Novartis to strengthen its compliance plan and cooperate with the ongoing investigation, and, through the plea and their corporate integrity agreement, bring real change to the sale and marketing of durable medical equipment. In doing so, Novartis joins other industry participants who have entered similar agreements to bring widespread reform to enteral sales practices.”

In a Stipulation filed at the time of the guilty plea, **OPI Properties, Inc.** agreed that it and its affiliate Novartis Nutrition Corporation (“NNC”) are wholly owned subsidiaries of Novartis Finance Corporation (“Novartis Finance”) which is a wholly owned subsidiary of Novartis Corporation (“Novartis”). OPI, NNC, and others engaged in businesses that included, inter alia, the manufacture, marketing, and sale of medical nutrition products, including enteral nutritional products to customers, including nursing homes. Enteral nutrition products are health care products intended to assist patients who, because of disease or other disorder, are not able to digest and absorb an oral diet. Enteral nutrition therapy products provide liquid nutrition through a tube into the stomach or small intestine

of such patients. Nursing homes would then provide the products directly to eligible Medicare beneficiaries, and, for patients covered by Part B of the Medicare program, submit claims to the Medicare program on behalf of the beneficiaries for reimbursement from Medicare.

The Stipulation states that Medicare, from time to time, audited the records of nursing homes and other suppliers to evaluate medical necessity and the amount of reimbursement to be provided for durable medical equipment (“DME”) including enteral products. Medicare, from time to time, also audited nursing homes and other suppliers to search for illegal remunerations, kickbacks, bribes and rebates that were provided to suppliers in violation of the Medicare anti-kickback statute.

The Stipulation further discusses that several managerial employees of NNC who had nationwide or regional responsibilities marketed enteral products to SMD. From time to time, NNC and others marketed the staff-saving benefits of enteral pumps to nursing homes, and offered to provide dietitians and support personnel to review the medical records of nursing home residents in connection with the suppliers’ claims for Medicare reimbursement for enteral products provided to such residents. **OPI Properties, Inc.** agreed that NNC employees discussed in the paragraph above engaged in conduct at SMD that violated material parts of Novartis’ Code of Conduct.

**OPI Properties, Inc.** admitted that from on or about September 12, 2000, through on or about July 24, 2001, in St. Clair County, within the Southern District of Illinois, and elsewhere, it and others caused the shipment of approximately ninety-five (95) enteral pumps to SMD in Swansea, Illinois. Enteral pumps are valuable to suppliers.

**OPI Properties, Inc.** and others characterized the enteral pumps to SMD as no charge items, provided “free” of charge. Defendant and others intended that and believed that the enteral products shipped to SMD were items for which payment was ultimately to be made in whole or in part under the Medicare program. Defendant and others cited lucrative Medicare reimbursement for the pumps

as reasons for SMD to buy products from Defendant and others. On occasion, an employee of NNC counseled customers regarding how Medicare reimburses suppliers for enteral products, and suggested to SMD that it submit charges to Medicare of \$162.99 per each enteral pump per month over the fifteen months that Medicare will provide reimbursement for an enteral pump.

As such, the Stipulation states that **OPI Properties, Inc.** and others, endeavored to influence, obstruct, and impede a federal auditor in the performance of official duties relating to SMD. Defendant and others did so by causing the sending of seven invoices for pump rental fees and a credit memo via the United States Postal Service, regular mail, to SMD. Defendant and others caused others to send a credit memo to SMD, in an amount approximately equal to the pump rental fees previously paid by SMD. Defendant and others advised SMD to present these documents to federal auditors in the event of a Medicare audit. Defendant and others intended and understood that each of the invoices and the credit memo would be subject to their unwritten agreement with SMD not to state, if asked by a federal auditor, that the purpose of the credit memo was to offset the pump rental fees previously paid by SMD. Defendant and others believed that, given the economic realities of the long term care of Medicare Part B beneficiaries in need of enteral therapy, that SMD or its affiliates would receive in excess of \$100,000 between 9/12/00 and 9/13/01 from Medicare Part B reimbursement payments. SMD did, in fact, receive in excess of \$100,000 from the United States during this time period.

Further, the Stipulation notes that **OPI Properties, Inc.** and others, on or about May 24, 2001, also offered SMD a written long term enteral sales contract offering a payment called a “conversion bonus,” “conversion and performance bonus,” and “an up-front conversion bonus of \$20,000” in exchange for SMD’s contractual agreement to purchase approximately \$1,213,460.22 worth of enteral products for ultimate use by Medicare beneficiaries over three years. As **OPI Properties, Inc.** and others acknowledged that there would be, in reality, no significant conversion costs for SMD, the

contract was an endeavor to influence, obstruct, and impede a federal auditor in the performance of the auditor's official duties regarding audits searching for illegal remunerations, kickbacks, bribes, and rebates paid in violation of the Medicare Anti-Kickback statute related to contracts, subcontracts, and grants relating to SMD. The three year contract's "conversion bonus" language was designed to conceal the contract's true purpose of inducement. As such, Defendant and others endeavored to influence, obstruct, and impede a federal auditor in the performance of official duties relating to SMD.

When discussing the bonus, the Stipulation notes that **OPI Properties, Inc.** and others undertook no accurate or specific investigation to determine what conversion costs, if any, SMD would incur. Defendant and others therefore did not know at the time they offered the bonus whether or by how much the offered bonus would be greater than any such purported conversion costs for SMD. Defendant and others offered a conversion bonus to SMD, a company that, in theory, had already been using NNC's products for many months, meaning any additional "conversion" would involve a customer who had already been purchasing enteral pumps and products for many months. Employees made oral statements and provided written deal paperwork to SMD suggesting that there would be no true conversion costs for SMD. Employees also stated to SMD that the purpose of the conversion bonus was an incentive to procure SMD's business. These marketing tactics were not approved sales practices for enteral contracts. Had NNC's management been aware of these marketing tactics, it would not have authorized the up-front payment.

In addition, in a civil settlement agreement between the United States, **OPI Properties, Inc.** and NNC, the United States contends that OPI and NNC caused others to submit false claims for payment to the Medicare Program for enteral pumps, and further contends that **OPI Properties, Inc.** and NNC agreed to provide enteral nutrition infusion pumps to suppliers for free in exchange for the suppliers' agreements to buy related enteral therapy products from NNC. The United States contends

that this practice violated the Medicare Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1) & (2), and the express terms of the Medicare durable medical equipment supplier application. **OPI Properties, Inc.** and NNC agreed to pay to the United States \$44,494,479 to release potential claims related to this conduct.

Finally, the Office of Inspector General for the U.S. Department of Health and Human Services contends that OPI Properties, Inc. and NNC violated the Anti-Kickback statute by offering SMD a conversion bonus and supplying SMD with enteral pumps at no cost to induce SMD to enter into an agreement to buy related enteral nutrition and other products. OIG has separate administrative authority to collect civil monetary penalties for such a violation under the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a. Under this authority, OIG will collect \$159,750 as a civil monetary penalty from OPI Properties, Inc. for its conduct, in exchange for an administrative release.

As part of the civil settlement, **OPI Properties, Inc.** will be permanently excluded from participation in the Medicare and Medicaid programs. NNC has also entered into a five-year corporate integrity agreement with the HHS Office of Inspector General, requiring NNC to reform the sales and marketing practices of its enteral feeding operations.

The case was investigated by the Federal Bureau of Investigation, the U.S. Postal Inspection Service, and the HHS Office of Inspector General. The criminal case was prosecuted by Assistant United States Attorney Andrew J. Lay and the civil case was handled by Assistant United States Attorney Gerald M. Burke.

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